PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 30 JUN 2006
WIPO PCT

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
PC28129A		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB2005/000673	10.03.2005	19.03.2004
International Patent Classification (IPC) or national classification and IPC		
INV. A61K9/70 A61K31/465 A61K9/00		
Applicant		
PFIZER HEALTH AB et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 9 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in celectronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
07.04.2005	27.06.2006
Name and mailing address of the international preliminary examining authority:	Authorized officer
European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Marttin, E Telephone No. +31 70 340-

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IB2005/000673

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-16 as originally filed

Claims, Numbers

1-15 as originally filed

Drawings, Figures

1-6 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 14-15 with regard to industrial applicability

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 14-15 with regard to industrial applicability

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished

☐ does not comply with the standard

the computer readable form ☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IB2005/000673

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	9,12
	No:	Claims	1-8,10,11,13-15
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-15
Industrial applicability (IA)	Yes:	Claims	1-13
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III.

Claims 14-15 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V.

1 Reference is made to the following documents (for relevant passages see Search Report):

D1 : US 5 415 629 A (HENLEY ET AL) 16 May 1995 (1995-05-16)
D2 : US 2001/033858 A1 (ZHANG JIE) 25 October 2001 (2001-10-25)
D3 : WO 96/00111 A (CYGNUS THERAPEUTIC SYSTEMS) 4 January 1996 (1996-01-04)
D4 : US 5 505 957 A (D'ANGELO ET AL) 9 April 1996 (1996-04-09)
D5: US-A-5 721 257 (BAKER ET AL) 24 February 1998 (1998-02-24)

2 Document D1 discloses a device for transdermal administration of nicotine for quitting smoking, comprising as a first part a iontophoretic electrode with a nicotine reservoir, and as a second part an ultrasonic element providing for additional administration of nicotine, the latter part being activatable by the user.

2.1 INDEPENDENT CLAIM 1
As can be seen from the above, document D1 discloses in combination all the features defined in independent claim 1. Hence the subject-matter of this claim is not new (Article 33(2) PCT).

2.2 INDEPENDENT CLAIMS 13-15
As can be seen from the above, document D1 discloses in combination all the features defined in independent claim 13. Hence the subject-matter of this claim is not new (Article 33(2) PCT). The same applies *mutatis mutandis* to the subject-matter

of independent claims 14 and 15.

3 Document D2 discloses a device for transdermal administration of nicotine comprising as a first part a transdermal nicotine patch, and as a second part a heating patch providing for additional administration of nicotine, the latter part being activatable by the user.

3.1 INDEPENDENT CLAIM 1

As can be seen from the above, document D2 discloses in combination all the features defined in independent claim 1. Hence the subject-matter of this claim is not new (Article 33(2) PCT).

3.2 INDEPENDENT CLAIMS 13-15

3.2.1 Document D2, which is considered to represent the most relevant state of the art, discloses a transdermal nicotine device from which the subject-matter of independent claim 13 differs in that the use of the device in smoking cessation or treating conditions suitable for treatment with nicotine is claimed

3.2.2 The problem to be solved by the present invention may therefore be regarded as the provision of an alternative use of the device.

3.2.3 In view of D5 the solution proposed in claim 13 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reason. The use of transdermal nicotine for the treatment of smoking cessation or treating conditions suitable for treatment with nicotine is disclosed in D5.

3.2.4 Therefore the features disclosed in D2 and D5 would be combined by the skilled person, without exercise of any inventive skills in order to solve the problem posed. The proposed solution in independent claim 13 thus cannot be considered inventive (Article 33(3) PCT). The same applies *mutatis mutandis* to the subject-matter of independent claims 14 and 15.

4 Document D3 discloses a device for transdermal administration of nicotine

comprising a first part that provides for passive diffusion and/or iontophoresis of nicotine, and a second part giving an electrical pulse activatable by the user to cause electroporation of the skin, thus providing for additional administration of nicotine.

4.1 INDEPENDENT CLAIM 1

As can be seen from the above, document D3 discloses in combination all the features defined in independent claim 1. Hence the subject-matter of this claim is not new (Article 33(2) PCT).

4.2 INDEPENDENT CLAIMS 13-15

4.2.1 Document D3, which is considered to represent the most relevant state of the art, discloses a transdermal nicotine device from which the subject-matter of independent claim 13 differs in that the use of the device in smoking cessation or treating conditions suitable for treatment with nicotine is claimed

4.2.2 The problem to be solved by the present invention may therefore be regarded as the provision of an alternative use of the device.

4.2.3 In view of D5 the solution proposed in claim 13 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reason. The use of transdermal nicotine for the treatment of smoking cessation or treating conditions suitable for treatment with nicotine is disclosed in D5.

4.2.4 Therefore the features disclosed in D3 and D5 would be combined by the skilled person, without exercise of any inventive skills in order to solve the problem posed. The proposed solution in independent claim 13 thus cannot be considered inventive (Article 33(3) PCT). The same applies *mutatis mutandis* to the subject-matter of independent claims 14 and 15.

5 DEPENDENT CLAIMS 2-12

Dependent claims 2-12 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT). The reasons

therefor are that the additional features of the said claims are either directly known from documents D1-D5, or are a combination of features obvious to the man skilled in the art in consideration of the disclosure of the prior art named in the present proceedings, or they concern only minor modifications which lie within the normal practice of the man skilled in the art.

7 For the assessment of the present claims 14-15 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item VIII.

1 CLARITY

1.1 The application does not meet the requirements of Article 6 PCT, because claims 3, 5, 10 and 13-15 are not clear.

1.2 Claim 3 is not clear since jet injection is not considered to be a transdermal administration route, the subject-matter of claim 3 is therefore inconsistent with claim 1 (Article 6 PCT).

1.3 Claim 5 does not meet the requirements of Article 6 PCT, because claim 5 is redundant. the first part of the device and the second part of the device of the subject-matter of claim 1 have already the feature in common that they provide for administration of nicotine.

1.4 Claim 10 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved, i.e. delivering nicotine during a

predefined period of time, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

1.5 Although claims 13-15 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness and as such do not meet the requirements of Article 6 PCT.